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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,653	04/17/2001	Wesley Paul Durkalski	20207-11	7384
7590 09/16/2004				
Wesley Paul Durkalski 12 John Street Charleston, SC 29403				
EXAMINER HAMILTON, MONPLAISIR G				
ART UNIT		PAPER NUMBER		
2135				

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/836,653	<b>Applicant(s)</b> DURKALSKI, WESLEY PAUL	
	<b>Examiner</b> Monplaisir G Hamilton	<b>Art Unit</b> 2135	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-8 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 11-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/13/04 has been entered.

The communication filed on 7/13/04 amended Claims 1, 4-8 and 11-14 and 20 cancelled Claims 2-3 and 9-10 and added Claims 21-22 have been added. Claims 1, 4-8 and 11-22 are pending.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-8 and 11-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Bleicher et al. (WO 99/63473).

Referring to Claims 1, 20 and 22:

Bleicher discloses a method for creating a customized clinical trial database management system for use in conducting a clinical trial, the method comprising:

providing a user with at least one question related to an anticipated use of the customized database management system, wherein the anticipated use comprises administration of a clinical trial (page 7, lines 10-20);

receiving at least one answer to the at least one question from the user (page 7, lines 10-20);

retrieving a set of clinical trial governance rules that govern the management of data acquired during a clinical trial (page 8, lines 1-10);

analyzing the at least one answer and the set of clinical trial governance rules (page 7, lines 10-15); and

generating the customized clinical trial database management system according to the analyzing of the at least one answer and the set of clinical trial governance rules (page 7, line 15-25), whereby the generated clinical trial database management system is configured to govern the conduct of a clinical trial and to manage data acquired during the clinical trial (page 7, lines 1-10).

Referring to Claim 8:

Bleicher discloses a creation system for generating a customized database management system used to conduct a clinical trial, the creation system comprising:

a computer configured to execute a first routine for asking a user at least one question related to a desired application for the customized clinical trial database management system and for receiving at least one answer to the at least one question from the user (page 7, lines 5-20);

the computer further configured to execute a second routine for retrieving a set of clinical trial governance rules that govern the management of data during a clinical trial (page 7, lines 10-20; page 8, lines 1-10);

the computer further configured to execute a third routine for processing an analysis of the at least one answer and the set of clinical trial governance rules (page 17, lines 3-15); and

the computer further configured to execute a fourth routine for generating the customized clinical trial database management system according to the analysis (col 12, lines 15-25; col 21, lines 5-10).

Art Unit: 2135

Referring to Claim 15:

Bleicher discloses a method for creating a clinical trials database management system, the method comprising:

providing information descriptive of a particular clinical trial (page 7, lines 10-15);

providing a first set of rules in accordance with clinical trials governing regulations (page 17, lines 4-30);

generating a second set of rules that conforms to the information and to the first set of rules (page 28, lines 1-10); and

generating the clinical trials database management system to be compliant with the second set of rules (page 21, lines 5-10).

Referring to Claims 4, 11:

Bleicher discloses the limitations of Claims 1, 8 above. Bleicher further discloses the set of the set of clinical trial governance rules is derived from clinical trials regulations (page 13, lines 1-5; page 19, lines 10-15; page 21, lines 5-15).

Referring to Claims 5, 12:

Bleicher discloses the limitations of Claims 1, 8 above. Bleicher further discloses the set of clinical trial governance rules governs the at least one answer (page 28, lines 1-10).

Art Unit: 2135

Referring to Claims 6:

Bleicher discloses the limitations of Claim 5 above. Bleicher further discloses generating creates a customized database management system that is in conformance with the set of clinical trial governance rules and the at least one answer (page 17, lines 1-15).

Referring to Claims 7, 14:

Bleicher discloses the limitations of Claims 1, 8 above. Bleicher further discloses providing a user with at least one question, the receiving at least one answer, the retrieving a set of clinical trial governance rules, the analyzing, and the generating are all performed on a common Web site (col 5, lines 4-10; Fig. 2-3).

Referring to Claim 13:

Bleicher discloses the limitations of Claim 8 above. Bleicher further discloses asking and receiving are handled by a dialogue box described by software executed by the computer (page 7, lines 10-20; Fig. 12A).

Referring to Claim 16:

Bleicher discloses the limitations of Claim 15 above. Bleicher further discloses the clinical trials database management system is contained within a Web site (page 10, lines 18-25).

Art Unit: 2135

Referring to Claim 17:

Bleicher discloses the limitations of Claim 16 above. Bleicher further discloses the clinical trials database management system is operable on the Web site (page 10, lines 18-25; Fig. 2-3).

Referring to Claim 18:

Bleicher discloses the limitations of Claim 15 above. Bleicher further discloses the information descriptive of a particular clinical trial includes a user name, and data collection specifications (page 22, lines 15-30; page 14, lines 15-30; Fig. 4a).

Referring to Claim 19:

Bleicher discloses the limitations of Claim 18 above. Bleicher further discloses the information descriptive of a particular clinical trial further includes specifications for data cleaning (page 16, lines 15-25; page 17, lines 20-30).

Referring to Claim 22:

Bleicher discloses the limitations of Claim 18 above. Bleicher further discloses the use of the customized clinical trial database management system comprises collecting data during trials of a new product and entering the collected data into the customized clinical trial database management system (page 10, lines 25-30; page 12, lines 15-25; page 15, lines 5-25).

*Prior Art*

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6108635 issued Herren, L. Tandy et al. Herren discloses a system including a set of software based Explorers, and a computer assisted methodology support the development of new medical interventions for diseases. The system includes Explorer modules for discovering proposed interventions, designing clinical trials, performing pharmacoeconomic analysis, and illustrating disease progression for various patients over time including creating disease progression tutorials for patients. The Explorers support a bottom-up or data driven methodology that enables a user, such as medical researcher, to mine data sources of clinical, biologic, expert or other types of data to discover, test, evaluate, and understand a proposed intervention and its impact on disease progression in different patient types. A Target Discovery Explorer assists the user in identifying leverage points in disease progression in relationship to various patient attributes and interventions, thereby identifying a proposed intervention for the disease. A Clinical Trials Explorer assists the user in designing clinical trials based through identification of combinations of patient attributes and intervention attributes that yield efficacious changes in selected disease progression measures. A Pharmacoeconomic Explorer enables the user to determine relative costs-benefits of a proposed intervention for patients, practitioners, and payers, including quality of life results for patients, practice results for practitioners, and financial payment results for payers. A Disease Progression Explorer enables the user to visually project disease progression for specified

Art Unit: 2135

patient attributes and interventions, in order to better understand and explain the effects of an intervention on a disease for such patients and their practitioners, and to select disease progression tutorials that are directed to the specific patient attributes and their corresponding effect on disease progression over time.

Art Unit: 2135

***Conclusion***

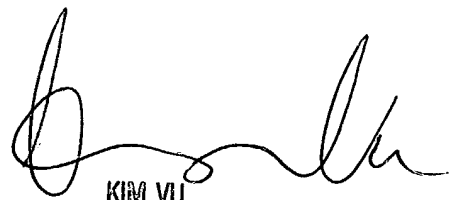
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monplaisir G Hamilton whose telephone number is (703) 305-5116. The examiner can normally be reached on Monday - Friday (8:00 am - 4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim Y Vu can be reached on (703) 305-4393. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

***NOTE: TC 2100 will be moved to Carlyle in October, 2004, the new telephone number for TC 2100 receptionist is 571-272-2100, my new telephone number is (571) 272-3852 and my supervisor's new number is (571) 272-3859.***

Monplaisir Hamilton



KIM VU  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 2100